

Project SDZ ASM 981: Safety summary infants

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Incidence density rate per 1000 months of monitoring for skin infections and non skin infections

AD: Infant population

Primary system organ class Preferred term	ASM 1% DB (N=495)	Vehicle DB (N=193)	Relative risk	95% CI	p-value	Total ASM 1% (N=1098)	(month follow-up=7686)
	(month follow-up=2581)	(month follow-up=596)					
-Occurrences of skin infection							
-Total	184	71.3	38	63.8	1.118 (0.80,1.61)	0.531	358 46.6
Bacterial							
-Total	66	25.6	15	25.2	1.016 (0.60,1.85)	0.956	120 15.6
ABSCESS	1	0.4	0				2 0.3
BACTERIAL INFECTION	16	6.2	4	6.7	0.924 (0.34,3.22)	0.887	25 3.3
CELLULITIS	1	0.4	0				3 0.4
ERYSIPelas	0		1	1.7			0
FOLLICULITIS	2	0.8	1	1.7	0.462 (0.04,9.93)	0.528	10 1.3
FURUNCLE	4	1.5	0				6 0.8
GENITAL INFECTION BACTERIAL NOS	1	0.4	0				1 0.1
IMPETIGO	28	10.8	8	13.4	0.808 (0.39,1.90)	0.595	55 7.2
ROSEOLA	5	1.9	1	1.7	1.155 (0.19,22.1)	0.896	7 0.9
SKIN AND SUBCUTANEOUS TISSUE ABSCESS NOS	0		0				1 0.1
SKIN BACTERIAL INFECTION	0		0				2 0.3
STYE	8	3.1	0				8 1.0
Fungal							
-Total	37	14.3	4	6.7	2.136 (0.86,7.13)	0.149	62 8.1
CANDIDA	8	3.1	0				16 2.1
CANDIDA NAPPY RASH	4	1.5	0				5 0.7
FUNGAL RASH NOS	1	0.4	0				1 0.1
ORAL CANDIDIASIS	14	5.4	2	3.4	1.616 (0.45,10.3)	0.525	23 3.0
SKIN FUNGAL INFECTION	9	3.5	2	3.4	1.039 (0.27,6.82)	0.961	16 2.1

incidence density in 1000 person months=(1000 * number of events during the study / total months of monitoring)
 Primary system organ classes are presented alphabetically, preferred terms are sorted within primary system organ class alphabetically.

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Incidence density rate per 1000 months of monitoring for skin infections and non skin infections

AD: Infant population

Primary system organ class Preferred term	ASM 1% DB (N=495) (month follow- up=2581)	Vehicle DB (N=193) (month follow- up=596)	Relative risk	95% CI	p-value	Total ASM 1% (N=1098) (month follow- up=7686)
TINEA CRURIS	1 0.4	0				1 0.1

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Incidence density rate per 1000 months of monitoring for skin infections and non skin infections

AD: Infant population

Primary system organ class Preferred term	ASM 1% DB (N=495)		Vehicle DB (N=193)		Relative risk	95% CI	p-value	Total ASM 1% (N=1098)	
	(month follow-up=2581)	(month follow-up=596)	(month follow-up=7686)					(month follow-up=7686)	
Parasitic									
-Total	5	1.9	2	3.4	0.577	(0.12, 4.03)	0.511	6	0.8
SCABIES INFESTATION	5	1.9	2	3.4	0.577	(0.12, 4.03)	0.511	6	0.8
Skin infection non specified									
-Total	27	10.5	10	16.8	0.623	(0.31, 1.35)	0.202	55	7.2
LOCALISED INFECTION	2	0.8	0					6	0.8
OMPHALITIS	0		0					1	0.1
PARONYCHIA	1	0.4	1	1.7	0.231	(0.01, 5.83)	0.300	3	0.4
RASH PUSTULAR	1	0.4	0					1	0.1
SKIN INFECTION	15	5.8	7	11.7	0.495	(0.21, 1.30)	0.124	22	2.9
SUPERINFECTION	7	2.7	2	3.4	0.808	(0.20, 5.42)	0.791	21	2.7
WOUND INFECTION NEC	1	0.4	0					1	0.1
Viral									
-Total	49	19.0	7	11.7	1.616	(0.78, 3.91)	0.235	115	15.0
CHICKENPOX	28	10.8	5	8.4	1.293	(0.54, 3.81)	0.596	58	7.5
HERPES SIMPLEX	2	0.8	1	1.7	0.462	(0.04, 9.93)	0.528	7	0.9
HERPES SIMPLEX DERMATITIS	3	1.2	0					10	1.3
HERPES ZOSTER	0		0					3	0.4
MOLLUSCUM CONTAGIOSUM	4	1.5	0					17	2.2
SKIN PAPILLOMA	1	0.4	0					3	0.4
VIRAL RASH	11	4.3	1	1.7	2.540	(0.49, 46.4)	0.372	17	2.2

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Incidence density rate per 1000 months of monitoring for skin infections and non skin infections

AD: Infant population

Primary system organ class Preferred term	ASM 1% DB (N=495)		Vehicle DB (N=193)		Relative risk	95% CI	p-value	Total ASM 1% (N=1098)	
	(month follow-up=2581)	(month follow-up=596)						(month follow-up=7686)	
Non skin infection									
-Total	919	356	209	351	1.015	(0.88,1.18)	0.842	2329	303
ACUTE TONSILLITIS	0	0	0	0				4	0.5
AMOEBOIC DYSENTERY	0	0	0	0				1	0.1
ANAL CANDIDIASIS	1	0.4	0	0				1	0.1
APPLICATION SITE INFECTION	0	0	0	0				9	1.2
ARTHRITIS VIRAL NOS	0	0	0	0				2	0.3
BRONCHIOLITIS	2	0.8	2	3.4	0.231	(0.03,1.92)	0.143	7	0.9
BRONCHITIS	74	28.7	20	33.6	0.854	(0.53,1.44)	0.532	202	26.3
BRONCHITIS CHRONIC	0	0	0	0				9	1.2
BRONCHITIS VIRAL	0	0	0	0				3	0.4
BRONCHOPNEUMONIA	0	0	1	1.7				2	0.3
BULLOUS IMPETIGO	0	0	0	0				1	0.1
BURN INFECTION	1	0.4	0	0				1	0.1
CANDIDIASIS	0	0	0	0				8	1.0
CELLULITIS STAPHYLOCOCCAL	1	0.4	0	0				1	0.1
CONJUNCTIVITIS	14	5.4	1	1.7	3.233	(0.65,58.6)	0.257	20	2.6
CONJUNCTIVITIS BACTERIAL	1	0.4	1	1.7	0.231	(0.01,5.83)	0.300	3	0.4
COXSACKIE VIRAL INFECTION	1	0.4	1	1.7	0.231	(0.01,5.83)	0.300	1	0.1
CROUP INFECTIOUS	4	1.5	0	0				11	1.4
CYSTITIS	0	0	0	0				1	0.1
DERMATITIS INFECTED	0	0	0	0				6	0.8
DIPHTHERIA	0	0	1	1.7				2	0.3
DYSENTERY NOS	1	0.4	0	0				1	0.1
EAR INFECTION	78	30.2	14	23.5	1.287	(0.75,2.37)	0.385	145	18.9
ECTHYMA	0	0	0	0				1	0.1

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Incidence density rate per 1000 months of monitoring for skin infections and non skin infections

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	(month follow-up=2581)	(month follow-up=596)					
ENTEROIASIS	0	0				1	0.1
ERYTHEMA INFECTIOSUM	0	0				4	0.5
FEBRILE CONVULSION	0	1	1.7			1	0.1
GASTROENTERITIS	38	14.7	10	16.8	0.877 (0.46,1.86)	0.713	90 11.7
GASTROENTERITIS ROTAVIRUS	1	0.4	0				4 0.5
GASTROENTERITIS VIRAL	3	1.2	1	1.7	0.693 (0.09,14.0)	0.751	8 1.0
GASTROINTESTINAL CANDIDIASIS	0	1	1.7				1 0.1
GASTROINTESTINAL INFECTION	3	1.2	3	5.0	0.231 (0.04,1.25)	0.073	18 2.3
HAND FOOT & MOUTH DISEASE	4	1.5	0				9 1.2
HELMINTHIC INFECTION NOS	2	0.8	0				2 0.3
HEPATITIS B	1	0.4	0				2 0.3
HERPANGINA	0	0					1 0.1
HERPETIC GINGIVOSTOMATITIS	2	0.8	0				2 0.3
HORDEOLUM	0	0					1 0.1
HUMAN HERPESVIRUS 6 INFECTION	0	1	1.7				2 0.3
IMMUNISATION REACTION	0	1	1.7				0
INFECTION	0	0					2 0.3
INFECTIOUS MONONUCLEOSIS	0	0					1 0.1
INFLUENZA	21	8.1	7	11.7	0.693 (0.31,1.76)	0.400	56 7.3
LARYNGITIS	5	1.9	0				17 2.2
LICE INFESTATION	0	0					3 0.4
LOWER RESPIRATORY TRACT INFECTION	16	6.2	4	6.7	0.924 (0.34,3.22)	0.887	19 2.5
LUNG INFECTION NOS	2	0.8	0				3 0.4
MALARIA NOS	1	0.4	0				1 0.1
MEASLES	2	0.8	0				2 0.3
MUMPS	0	0					2 0.3

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	(month follow-up=2581)	(month follow-up=596)	(month follow-up=810)	(month follow-up=105)				(month follow-up=7686)	
NAIL BED INFECTION NOS	1	0.4	0					1	0.1
NASOPHARYNGITIS	330	128	68	114	1.121	(0.87, 1.47)	0.392	810	105
OTITIS EXTERNA	0		0					1	0.1
OTITIS EXTERNA (EXC BOIL OF MEATUS) NOS	0		0					1	0.1
OTITIS MEDIA	56	21.7	12	20.1	1.078	(0.60, 2.11)	0.814	159	20.7
OTITIS MEDIA ACUTE	0		0					1	0.1
PARASITIC INFECTION INTESTINAL	0		0					1	0.1
PARASITIC INFECTION NOS	1	0.4	0					2	0.3
PENILE INFECTION NOS	1	0.4	0					1	0.1
PERIANAL ABSCESS	0		0					1	0.1
PERITONSILLAR ABSCESS NOS	1	0.4	0					4	0.5
PHARYNGITIS	15	5.8	2	3.4	1.732	(0.49, 11.0)	0.466	32	4.2
PHARYNGITIS STREPTOCOCCAL	3	1.2	0					5	0.7
PHARYNGITIS VIRAL NOS	0		0					1	0.1
PHARYNGOTONSILLITIS	0		0					1	0.1
PNEUMONIA	6	2.3	2	3.4	0.693	(0.16, 4.73)	0.653	18	2.3
PSEUDOCROUP	0		0					3	0.4
PYELONEPHRITIS NOS	1	0.4	0					1	0.1
RESPIRATORY SYNCYTIAL VIRUS INFECTION NOS	0		0					1	0.1
RESPIRATORY TRACT INFECTION	8	3.1	1	1.7	1.847	(0.34, 34.3)	0.563	23	3.0
RESPIRATORY TRACT INFECTION VIRAL	0		0					1	0.1
RHINITIS	0		0					59	7.7
RHINITIS INFECTIVE	0		0					1	0.1
RUBELLA	0		1	1.7				2	0.3

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SALMONELLA INFECTION NOS	2	0.8	0			2 0.3
SCARLET FEVER	3	1.2	0			4 0.5
SECONDARY INFECTION NOS	0	0				1 0.1
SINUSITIS NOS	10	3.9	3 5.0	0.770 (0.24, 3.43)	0.691	18 2.3
STAPHYLOCOCCAL INFECTION	0	0				4 0.5
SUBCUTANEOUS ABSCESS	0	0				1 0.1
TINEA CAPITIS	1	0.4	0			2 0.3
TONSILLITIS	27	10.5	5 8.4	1.247 (0.52, 3.68)	0.650	63 8.2
TRACHEITIS NOS	5	1.9	0			5 0.7
UPPER RESPIRATORY TRACT INFECTION	155	60.1	39 65.4	0.918 (0.65, 1.32)	0.632	368 47.9
URINARY TRACT INFECTION	6	2.3	0			11 1.4
VAGINAL CANDIDIASIS	1	0.4	0			1 0.1
VIRAL DIARRHOEA	0	0				1 0.1
VIRAL INFECTION	7	2.7	6 10.1	0.269 (0.09, 0.84)	0.018	23 3.0
VIRAL UPPER RESPIRATORY TRACT INFECTION	0	0				1 0.1

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